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SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/463,740 06/05/95 VON BORSTEL

12MC/0402

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ARLINGTON VA 22201

EXAMINER
EDMUND G

ART UNIT	PAPER NUMBER
	6

DATE MAILED: 04/02/96

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☒ Responsive to communication filed on 12/4/95 ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), — days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- | | |
|---|---|
| 1. <input checked="" type="checkbox"/> Notice of References Cited by Examiner, PTO-892. | 2. <input type="checkbox"/> Notice of Draftsman's Patent Drawing Review, PTO-948. |
| 3. <input type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449. | 4. <input type="checkbox"/> Notice of Informal Patent Application, PTO-152. |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474. | 6. <input type="checkbox"/> _____ |

Part II SUMMARY OF ACTION

1. ☒ Claims 41 and 58-65 are pending in the application.
Of the above, claims _____ are withdrawn from consideration.
2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 41 & 58-65 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with Informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____, has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

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08/463,740
PTOL-328 (Rev. 2/83)

EXAMINER'S ACTION

Serial Number: 08/463,740

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Art Unit: 1211

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1211.

All 35 USC statutes not cited in this Office action can be found cited in full in the first Office action mailed August 2, 1995.

The rejection of claim 41 under 35 USC 112, first paragraph, has been withdrawn in view of the amendments to the claim.

Claims 41 and 58 - 65 are rejected under 35 U.S.C. § 103 as being unpatentable over Von Borstel et al. (WO 89/03837) in view of Chu et al. (4,613,604).

The claims are directed to a composition comprising acylated uridine, cytidine, or orotic acid and an inhibitor of uridine phosphorylase.

Von Borstel et al. discloses compositions comprising acylated uridine, cytidine, or orotic acid which are useful as prodrugs for increasing serum and intracellular free uridine (claims 30 - 39). Von Borstel et al. does not mention the combined use of said acylated pyrimidine nucleosides and an inhibitor of uridine phosphorylase. However, Chu et al. does teach the use of uridine phosphorylase inhibitors in order to potentiate the chemotherapeutic effect of pyrimidine nucleoside

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analogues such as 5-fluorouridine (column 2, lines 36 - 59) by elevating the levels of free uridine. Therefore, it would have been obvious to the person of ordinary skill in the art at the time of the invention to have combined the prodrugs of uridine disclosed by Von Borstel et al. with the uridine phosphorylase inhibitors taught by Chu et al. for the purpose of elevating even higher the free uridine levels in the serum and inside the cells. Thus, the claimed compositions are prima facie obvious in the absence of clear and convincing evidence to the contrary.

Claim 65 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 65 is rendered vague and indefinite by the language "including" in line 3 and the phrase "including but not limited to" in line 8. This type of language is appropriate for the specification but in the claims it fails to specify clearly the metes and bounds of the invention. One way to address this problem is to add independent claims which contain the limitations listed after the word "including".

The Information Disclosure Statement has not been initialed because the examiner cannot locate copies of the cited references in the parent cases. New copies of these references are requested.

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No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kunz, whose telephone number is (703) 308-4623. The examiner can normally be reached on Tuesday through Friday from 6:30 AM to 4:00 PM. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Kight, can be reached on (703) 308-0204. The fax phone number for this Group is (703) 305-4556.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

Gary L. Kunz, Ph.D.
March 30, 1996

Gary L. Kunz
GARY L. KUNZ
PRIMARY EXAMINER
GROUP 1200
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